THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Robert J. Marshall	
Serial No:	10/722,777	Group No: 1651
Filing Date:	26 November 2003	Examiner: Thane E. Underdahl
Customer No.	51079	Confirmation No.: 7232
Title:	**STABILIZED DIHYDROLIPOIC ACID AND METHOD OF PRODUCING SAME**	

DECLARATION UNDER RULE 37 CFR §1.132

I, Dr. Dinesh-Kumar Patel, declare as follows:

1. I obtained a B. Sc. degree in Medicinal Chemistry in 1989, a M. Sc. degree in Pharmacology in 1990, and Ph D. degree in Chemistry in 1992, all from Loughborough University, Leicestershire, United Kingdom. I participated in post-doctoral study focused on identifying new modalities in pain research at the University of Arizona from 1992-1994.

2. Since 1994 I have worked continuously in the field of chemistry in the analysis of natural products, complex blends of botanical extracts, and semi-synthetic vitamins. I was employed by Integrated Biomolecule Corporation from 1994 to 2005 by as Director of Peptide Chemistry (1994-2000); Director of Chemistry (2000-2002); and Director of Chemistry/Analytical Chemistry (2002-2005). I am currently employed by Atlas Bioscience, Inc. as the Laboratory Director (2006-present).

3. I have co-authored over 20 scientific publications selected examples of which are detailed in my Curriculum Vitae, a copy of which is attached. I am also a co-inventor of U.S. Patents 6,355,230 and 6,551,630 directed to dietary supplements containing material of the genera *Prunus* and use thereof.

4. My research interests include the development of methods for the synthesis, isolation, analysis, and quantification of various components and/or low-level contaminants in pharmaceutical, phytochemical, and dietary supplement materials.

5. I have reviewed and understood U.S. Patent Application Serial No. 10/722,777 to Robert J. Marshall ("Marshall application"), U.S. Patent 6,368,617 to Hastings et al. ("Hastings), "Enantioselective phamacokinetics and bioavailability of different racemic α-lipoic acid formulations in healthy volunteers," European Journal of Pharmaceutical Sciences, 4 (1996) 167-174 by Hermann et al. ("Hermann"), "The Pharmacology of the Antioxidant Lipoic Acid" 1997 by Biewenga ("Biewenga"), "Probiotics: From Myth to Reality. Demonstrations of Functionality in Animal Models of Disease and in Human Clinical Trials," 1999 by Dunne et al. ("Dunne"), "Probiotics as Biotherapeutic Agents: Present Knowledge and Future Prospects," 2003 by Mercenier et al. ("Mercenier"), and a translation of German Patent Application Publication No. DE 19730538 by inventor Niggemann produced by automated process provided by the European Patent Office on January 25, 2010 ("Niggemann").

6. I have reviewed two Office Actions from the United States Patent and Trademark Office dated February 2, 2010 and September 21, 2010 in the Marshall Application, and the response to the February 2, 2010 Office Action dated July 2, 2010.

7. I believe that Claims 4-22 and claims 24-26 of the Marshall Application as presented in the July 2, 2010 response are directed to an important and patentable improvement over the subject matter described in Hastings, Hermann, Biewenga, Dunne, Mercenier and Niggemann.

8. In the Office Action dated September 21, 2010, I noted the following statements:

Page 3, 1st paragraph:

> "The last limitation 'an effective amount of a probiotic activity halting agent to halt probiotic activity in the composition' when interpreted broadly reads on any amount of such agent. The Applicant appears to construe the claim to mean that the while the probiotic activity is halted the organism is still live and vital. However this is not the case."

Page 6, last paragraph:

"In this regard, Applicant appears to equate 'halting activity' with killing or completely deactivating. However, all that 'halting' requires is 'suspension of activity' for however long or short a period of time is desired. Therefore, the references applied clearly meet this limitation regardless of the actual amount of ethanol contained therein, since the amount provided is effective in halting probiotic activity at least temporarily."

9. Based on my experience in the field of biochemistry and its application to the production of pharmaceutical and dietary supplement compositions, I understand the terms "halt" and "halting" in relation to probiotic activity in a microbiological culture composition such as those described in the Marshall Application to mean a complete and permanent cessation of the probiotic activity within the composition, in contrast to an incomplete or temporary cessation of probiotic activity which would leave at least some of the probiotic organisms viable.

10. I believe that one of ordinary skill in the field of biochemistry would use terms other than "halt" for a temporary or incomplete cessation of probiotic activity in the context of the subject matter of the Marshall Application, such as "suspend," "retard," or "reduce."

11. On page 4 of the Marshall Application, I noted the following statements:

Lines 6-11:

"The invention still further comprehends a process for preparing a stabilized dihydrolipoic acid (DHLA) compound including dispensing a microbiological culture media including at least one live probiotic organism, R-lipoic acid and at least one nutritive agent in distilled water to form a broth, incubating the broth at a predetermined temperature for a select period of time to induce probiotic activity; adding organic ethanol to halt the probiotic activity, and separating the stabilized DHLA from the broth."

Lines 18-20:

"The present invention further provides a stabilized dihydrolipoic acid (DHLA) compound derived from a once living source for use in a medicament or a nutritional supplement."

12. I further note that reference to the "once living" nature of the source material used in creating the stabilized DHLA compound is further made on: page 1, line 3; page 3, line 8; page 5, lines 5, 8, and 12; and original Claims 2 and 3.

13. I believe these statements communicate that the step of adding an agent "to halt the probiotic activity" in the microbiological culture compositions described in the Marshall application must completely end all probiotic activity in the composition so as to end the "living" or viable nature of the source material of the DHLA.

14. In the Office Action dated September 21, 2010, at page 3, 1st paragraph, I further noted the following statement:

> "The Examiner searched the Specification for guidance as to the 'effective amount' and did not readily find a number or formula explicitly defining what is an "effective amount of agent."

15. As I have declared, it is my belief that the Marshall Application discloses that the amount of agent used to halt probiotic activity is an amount sufficient to end probiotic activity in a given composition. This amount would depend on the probiotic nature of the composition and the number of the probiotic organisms present, as well as the strength of the agent with respect to the agent's ability to end probiotic activity. Determining the amount of agent necessary to end probiotic activity (i.e., to effectively render the organisms non-viable) is a matter of routine measurement of probiotic activity in the composition and adjustment of the amount of agent used can be accomplished without undue experimentation.

I acknowledge that willful and false statements are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and may jeopardize the validity of this Marshall application or any patent issuing from it. I declare under penalty of perjury under the laws of the United States that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.

Dinesh-Kumar Patel

November 4th 2010

Date